VERMONT

Vermont Health Access
Pharmacy Benefit Management Program
DUR Board Meeting Minutes: 10/13/09

Board Members:

Michael Scovner, M.D., Chair
Lynne Vezina, R.Ph.
Kathleen Boland, Pharm.D.
Norman Ward, M.D.
Cheryl Gibson, M.D.
Richard Harvie, R. Ph.

Staff:

Michael Farber, M.D. OVHA
Diane Neal, R.Ph., (MHP)
Nancy Miner, (MHP)
Nancy Hogue, Pharm.D. (MHP)
Jennifer Mullikin, OVHA
Stacey Baker, OVHA
Judy Jamieson, OVHA

Guests:

Matt Badalucco, Merck
Amy Finn, Merck
Mouhzmed Gueye, Roche Pharmaceutical
Mark Kaplan, Abbott
Craig Lemley, Amylin
Kelley Mackison, Johnson & Johnson
Paul McDermott, Centecor Ortho Biotech
Steven McRae, Genentech
Bob Meany, Takeda Pharmaceuticals
Chris Michaels, Elan
Tim Nies, GSK
Carl Possidente, Pfizer
Gary Prevost, PriCara
Wayne Smith, Jazz Pharma
Angelo Valeri, Novartis

Michael Scovner, M.D. Chair, called the meeting to order at 7:00 p.m. at the DUR Board meeting site in Williston.

1. Executive Session:

- An executive session was held from 6:30 until 7:00 p.m. to discuss Medicaid OBRA'90/Supplemental Rebates and Agreements as provided by 33 VSA § 1998(f)(2).

2. Introductions and Approval of DUR Board Minutes:

- Introductions were made around the table. Dr. Michael Farber was introduced as the new Medical Director. Dr. Farber comes to Vermont from California Medicaid (MediCal).
- The September 2009 meeting minutes were amended so that the quantity limit on Uloric® would read "1 tablet per day". The amended minutes were accepted.

Public Comment: No public comment.

3. OVHA Pharmacy Administration Updates: *Vicki Loner - Deputy Director, OVHA*

- No administration update.

4. Medical Director Update: *Michael Farber, M.D. – Medical Director*

- Clinical Programs Update: No updates to report.
- Prescriber Comments: No comments to report.

5. Follow-up items from Previous Meeting: *Diane Neal, R.Ph., MedMetrics Health Partners (MHP)*

- Kapidex® Communications (Proton Pump Inhibitors)
  The Kapidex®/Prevacid® communication sent to pharmacies was shared with the DUR Board. The Board requested that the communication to be sent to prescribers include dosing information. The Board also asked that MedMetrics ensure that the messaging sent to pharmacies when Prevacid® prescriptions are rejected clearly list PDL preferred alternatives.

Public Comment: No public comment.

Board Decision: None needed.

- Vectical® (calcitriol) Topical Ointment
  Deferred until next meeting. Unable to obtain input from a dermatologist to date.

6. Clinical Update: Drug Reviews: *Diane Neal, R.Ph.(MHP)*
(Public comment prior to Board action)
Note: All drug/criteria decisions will be reflected in the next PDL and/or Clinical Criteria update.

Abbreviated New Drug Reviews

- Aplenzin® (buproprion extended release) Tablet: It was recommended that coverage would require PA with the criteria for approval being that the patient has had a documented inadequate response to Wellbutrin XL AND the patient has had a documented side effect, allergy, or inadequate response to at least 2 different antidepressants from the SSRI, SNRI and/or Miscellaneous Antidepressant categories (may be preferred or non-preferred). A quantity limit of one tablet per day was recommended.

Public Comment: No public comment.

Board Decision: The Board unanimously approved the MHP recommendations noted above.

Full Drug Reviews

- Rapaflo® (silodosin) Capsule: It was recommended that coverage would require PA with the criteria for approval being that the patient has had a documented side effect, allergy or treatment failure with two preferred drugs (preferred drugs include doxazosin (generic), terazosin (generic), Flomax® and Uroxatral®). A quantity limit of one capsule per day was recommended.

Public Comment: No public comment.

Board Decision: The Board unanimously approved the MHP recommendations noted above.

- Simponi® (golimumab) Prefilled Injection: It was recommended that coverage would require PA due in part to its lack of proven superiority to other available agents and also to its cost compared to these other agents.

Public Comment: Paul McDermott, Centecor Ortho Biotech – Commented on the cost of Simponi® and its clinical attributes and ease of administration.

Board Decision: Due to some inaccuracies in the monthly cost of therapies within this drug category reported in the review, the Board moved to table discussion of Simponi® at this time and to continue

discussion next month. The Board also requested that the drugs considered to belong to the DMARD category be outlined clearly.

- Toviaz® (fesoterodine) ER Tablet: It was recommended that coverage would require PA with the criteria for approval being that the patient has had a documented side effect, allergy, or treatment failure with oxybutynin (short acting) AND the patient has had a documented side effect, allergy, or treatment failure with 2 preferred long-acting urinary antispasmodic agents. A quantity limit of one tablet per day was recommended.

Public Comment: No public comment.

Board Decision: The Board unanimously approved the MHP recommendations noted above.

7. Review of Newly-Developed/Revised Clinical Coverage Criteria: *Diane Neal, R.Ph, (MHP)*
(Public comment prior to Board action)

- Influenza Medications:
  Presented to the DUR Board as information was a letter from CMS to State Health officials concerning vaccinations and antiviral medications for 2009 H1N1. PA criteria have been removed for antivirals at the request of the VT Department of Health though quantity limits remain. A general update on the state of drug supplies and management of the class was presented.

Public Comment: No public comment.

Board Decision: None needed.

- Ossification Enhancers:
  See below for individual drug subclasses. In addition, it was recommended that the length of authorization for non-preferred drugs in this class be changed from lifetime to 3 years.

Public Comment: No public comment.

Board Decision: The Board approved the recommended change.

8. Drug Classes – Annual Review:
(Public comment prior to Board action)

- Bisphosphonates: Since there is no data to conclusively recommend one oral bisphosphonate over another, no changes are recommended in this category. Alendronate (generic) and Boniva® are the preferred oral products. It was recommended that 2 new indications be added to the clinical criteria accepted indications for Reclast® injection to also include that the patient is male with a diagnosis of osteoporosis or the patient has a diagnosis of glucocorticoid induced osteoporosis.

Public Comment: No public comment.

Board Decision: The Board approved the changes recommended above.

- Calcitonins: It was recommended that both Miacalcin® and Fortical® continue to be available as preferred products. The generic formulation that is AB equivalent to Miacalcin® should be listed

as non-preferred with the criteria for approval being that the patient has a documented intolerance to the brand product.

Public Comment: No public comment.

Board Decision: The Board unanimously approved the MHP recommendations noted above.

- Parathyroid Hormones: It was recommended that the criteria for approval of Forteo® (the only drug in this class) be modified to read "treatment failure is defined as documented continued bone loss or fracture after one or more years of treatment with a preferred bisphosphonate".

Public Comment: No public comment.

Board Decision: The Board approved the MHP recommended change.

9. RetroDUR: *Diane Neal, R.Ph, (MHP)*

- Cough and Cold Products in Children Less than 2 years old
  In January of 2008, the FDA issued a public health advisory, warning of the risk of using cough and cold medications in patients under the age of 2, due to the risk of potentially life threatening adverse effects. Due to this warning, a prior authorization for all cough and cold products was implemented for the Office of Vermont Health Access for patients under 2 years of age. In order for a PA to be approved, the doctor must acknowledge the FDA's warning regarding the risks of using these medications in children less than 2 years of age, and document that the medical necessity for use of the cough/cold product in their patient outweighs the risks as described in the FDA alert. Since the implementation of the PA, the number of claims has decreased from 62 to 2 per cold season (October 1 through April 30).

Public Comment: No public comment.

Board Decision: The Board agreed that the current criteria for prior authorization for cough and cold products for children under the age of 2 years old are clinically appropriate and that no changes are required.

- Future Topics: A discussion of possible future RetroDUR topics was held. There was still considerable interest in going back and looking at short acting beta-agonist overuse in patients who are not on a regularly taken controller medication. The Board was asked to think about other possible topics.

10. New Drug Product Plan Exclusions: *Diane Neal, R.Ph, (MHP)*

This will become a quarterly agenda topic so will be discussed at the December meeting.

11. Updated New-to-Market Monitoring Log: *Diane Neal, R.Ph, (MHP)*

- The log is posted on the web site. This log shows new entries in the market highlighted in red. The log is informational only. Suggested dates for review are to be used as a guide only. The actual date of review will depend on the complexity of the agenda.

12. General Announcements: *Diane Neal, R.Ph, (MHP)*

FDA Safety Alerts

- Sitagliptin – pancreatitis:
  FDA is revising the prescribing information for Januvia (sitagliptin) and Janumet (sitagliptin/metformin) to include information on reported cases of acute pancreatitis in patients using these products. Prescribers should be aware of the possibility for and monitor for the emergence of the signs and symptoms of pancreatitis such as nausea, vomiting, anorexia, and persistent severe abdominal pain, sometimes radiating to the back. No changes to clinical criteria are recommended.

Public Comment: No public comment.

Board Decision: None needed

- Tysabri - More cases of PML:
  The FDA continues to receive reports of progressive multifocal leukoencephalopathy (PML) in patients receiving Tysabri. Tysabri was approved by the FDA for the treatment of relapsing forms of multiple sclerosis (MS) in November 2004 and for moderately to severely active Crohn's disease in January 2008. The risk for developing PML appears to increase with the number of Tysabri infusions received. At this time, the FDA is not requiring changes regarding PML to the Tysabri prescribing information or to the Tysabri risk management plan, called the TOUCH Prescribing Program. No changes to clinical criteria are recommended.

Public Comment: No public comment.

Board Decision: None needed

13. Adjourn: Meeting adjourned at 8:30 p.m.

Next DUR Board Meeting
Tuesday, November 10, 2009
7:00 - 9:00 p.m.*
EDS Building, OVHA Conference Room
312 Hurricane Lane, Williston, VT
(Entrance is in the rear of the building)

* The Board meeting will begin at 6:30 p.m. and the Board will vote to adjourn to Executive Session to discuss Medicaid OBRA'90/Supplemental Rebates and Agreements as provided by 33 VSA § 1998(f)(2). The Executive Session is closed to the public.